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EXAMINER
LEONARDO, II

33M1/1117
PRAVEL HEWITT KIMBALL AND KRIEGER
1177 WEST LOOP SOUTH
10TH FLOOR
HOUSTON TX 77027-9095

ART UNIT PAPER NUMBER

3309

DATE MAILED: 11/17/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-29 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-3, 7-13, 17-24, 28, 29 are rejected.
5. ☒ Claims 4, 5, 6, 14, 15, 16, 25, 26, 27 are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Part III DETAILED ACTION

1. Claims 8, 10, 18, 20 & 29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 8, line 4, there is no antecedent basis for "lower portion"; it should be --lower section--.

With respect to claims 10 & 20, "non-articulating bone bolt" is indefinite. Applicant should claim what the bolt *is* and not what the bolt *is not*.

With respect to claim 18, line 4, there is no antecedent basis for "lower portion"; it should be --lower section--.

With respect to claim 29, line 4, there is no antecedent basis for "lower portion"; it should be --lower section--.

2. Claims 1, 11 & 21 are objected to because of the following informalities:

Claim 1, line 2, "at least one open portions" should not be in the plural; it should read as --at least one open portion--. Line 9, "set" should be --said--.

Claim 11, line 10, "set" should be --said--.

Claim 21, line 2, "at least one attachment portions" should be --at least one attachment portion--. Line 4, there is no antecedent for "the attachment portion"; it should be --the at least one attachment portion-- or --each attachment portion--. Line 9, "set" should be --said--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 11, 12, 13, 17, 18, 19, 21, 22, 23, 24, 28 & 29 are rejected under 35 U.S.C. § 102(b) as being anticipated by Harms et al. (U.S. Patent No. 4,946,458).

With respect to claim 11, 21 & 22, Harms et al. discloses: a spinal rod 39 connected to a plurality of rod/bolt connectors 3, where each connector has an open portion 19 with each portion allowing placement of a fastener therethrough (See Harms et al. at figure 1); a series of fasteners 1 attachable to each of said connectors at each connector portion, at least one of said fasteners including a multi-angle fastener having a pair of fastener sections configured to be angled relative to one another comprising: an upper section 16 having a central longitudinal axis and an outer surface; a lower section 2 having a central longitudinal axis and an outer surface having bone attachment means 4 configured to be surgically implantable into a patient's bone tissue; and joint means for connecting the upper and lower sections together; said joint means including corresponding mating surfaces 8 & 14 configured to articulate with each other sufficiently to allow the upper and lower sections to angle relative to one another.

With respect to claims 12, 13, 17, 18, 19, 23, 24, 28 & 29 Harms et al. discloses: the mating surfaces including corresponding concave 8 and convex 14 surfaces shaped to allow

for a rotational movement of the upper and lower section, with the corresponding concave and convex surfaces providing a semi-rigid connection within the multi-angle fastener; rotational movement of the upper and lower sections allowing for a range on angulation in a range of about between 20 -70 degrees relative to the central longitudinal axes of the upper and lower sections (See Harms et al. at column 5, lines 17 - 24); a sleeve 9 configured to surround the joint means wherein the sleeve is cylindrical in shape and includes an inner surface with threading 10 on a portion of the inner surface, said sleeve threading engaging a threaded portion on the outer surface of the lower section of the fastener 2; and a series of fasteners including at least two multi-angle fasteners (See Harms et al. at column 1, lines 17 - 20).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

6. Claims 1, 2, 3 & 7 - 10 are rejected under 35 U.S.C. § 103 as being unpatentable over Harms et al. (U.S. Patent No. 4,946,458) in view of Small et al. (U.S. Patent No. 5,129,899).

With respect to claims 1, 2, 3, 7 & 8, Harms et al. discloses a series of multi-angle fasteners 1 having a pair of fastener sections configured to be angled relative to one another comprising: an upper section 16 having a central longitudinal axis and an outer surface; a lower section 2 having a central longitudinal axis and an outer surface having bone attachment means 4 configured to be surgically implantable into a patient's bone tissue; and joint means (See Harms et al. at figure 1.) for connecting the upper and lower sections together; said joint means including corresponding mating surfaces 8 & 14 configured to articulate with each other sufficiently to allow the upper and lower sections to angle relative to one another. Harms et al. also discloses: the mating surfaces including corresponding concave 8 and convex 14 surfaces shaped to allow for a rotational movement of the upper and lower sections, with the corresponding concave and convex surfaces providing a semi-rigid connection within the multi-angle fastener; a multi angle bolt having rotational movement of the upper and lower sections allowing for a range on angulation in a range of about between 20 -70 degrees relative to the central longitudinal axes of the upper and lower sections (See Harms et al. at column 5, lines 17 - 24); a sleeve 9 configured to surround the joint members wherein the sleeve is cylindrical in shape and includes an inner surface with threading 10 on a portion of the inner surface, said sleeve threading engaging a threaded portion on the outer surface of the lower section of the fastener 2.

Harms et al. does not disclose a bone plate construct having a bone plate member having at least one open portion where open portion allows placement of a series of fasteners or a series of fasteners attachable to said plate member at said open portions. Small et al.

teaches a bone plate member having at least one open portion, said open portions allowing placement of a series of fasteners therethrough at spaced apart positions along a length of the open portions and a series of fasteners attachable to said plate member at said open portions (See Small et al. at figure 2.).

It would have been obvious to substitute a bone plate with a least one open portion, such as taught by Small et al., for the spine rod of Harms et al. because a bone plate connection would provide for a more rigid connection than a spine rod and also provide a lower profile along the spine which is beneficial to the patient.

With respect to claims 9 & 10, Harms et al. discloses a series of fasteners including at least two multi-angle fasteners (See Harms et al. at column 1, lines 17 - 20), but does not show a series of fasteners wherein at least one is a non-articulating bone bolt. Small et al. shows at least one non-articulating bone bolt (See Small et al. figure 2.). It would have been obvious to include at least one non-articulating bone bolt in the series of fasteners disclosed in Harms et al. because not all vertebrae are positioned in a manner that would require the special angulation offered by a multi angle bone bolt and as such these vertebrae would require a bolt that was non-articulating.

7. Claim 20 is rejected under 35 U.S.C. § 103 as being unpatentable over Harms et al. in view of Small et al. Harms et al. does not disclose a series of fasteners wherein at least one is a non-articulating bone bolt. Small et al. shows at least one non-articulating bone bolt (See Small et al. figure 2.) used as part of an internal fixator for the spine. It would have been

obvious to include at least one non-articulating bone bolt in the series of fasteners in Harms et al., such as taught by Small et al., because not all vertebrae are positioned in a manner that would require the special angulation offered by a multi angle bone bolt and as such these vertebrae could be accommodated by a bolt that is non-articulating. Such non-articulating bolts are well-known in the internal fixator art.

Allowable Subject Matter

8. Claims 4, 5, 6, 14, 15, 16, 25, 26 & 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark S. Leonardo whose telephone number is (703) 308-1320. The examiner can normally be reached on Monday - Thursday from 7:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Pellegrino, can be reached on (703) 308-0871. The fax phone number for this Group is (703) 305-3590.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.


MSL

October 26, 1995


TAMARA L. GRAYSAY
PRIMARY EXAMINER
GROUP 3300